REMARKS

Claims 1-118 are pending in this application. Applicants cancel claims 1-64, without prejudice to pursue the subject matter in one or more related applications.

The Examiner has required an election under 35 U.S.C. § 121 of one of the following groups:

Group I: Claims 1-37, drawn to a method of delivering a substance into an intradermal space at a depth of 0.3-2 mm, classified in class 604, subclass 506.

Group II: Claims 38-45, drawn to a microneedle, classified in class 604, subclass 264.

Group III: Claims 46-64, drawn to a method of contacting a subject's skin with a device to deliver a bioactive substance to a dermal space, classified in class 604, subclass 500.

Group IV: Claims 65-74, drawn to a method of injecting a substance into the dermis to achieve improved systemic absorption relative to subcutaneous injection, classified in class 604, subclass 506.

Group V: Claims 75-96, drawn to a method of injecting growth hormone, heparin, or dopamine receptor agonist into the dermis to obtain systemic absorption, classified in class 604, subclass 507.

Group VI: Claims 97 and 98, drawn to an electroporation or thermal poration device classified in class 604, subclass 20.

Group VII: Claims 99-118, drawn to a method of administering a substance to the dermis to achieve improved systemic absorption as compared to bolus subcutaneous administration, classified in class 604, subclass 506.

The Examiner contends that the inventions of Groups IV, V, and VII are distinct from each other. Applicants respectfully traverse the Restriction Requirement and respectfully request a modification of the requirement so that Groups IV, V, and VII be combined, and examined together in the instant application. For the reasons below, the

subject matter of the claims merit examination in a single application. The claims of Groups IV, V, and VII are all directed toward methods for administration of a substance (*e.g.*, a growth hormone, a low molecular weight heparin, or a dopamine receptor agonist) to a mammal by either delivering, including selective delivery and injection, into the dermal compartment of the mammal. The methods of the claims do not require different substances, as the *same substances* are administered in each of the Groups. Similarly, methods of administering the substances to mammals are the *same*. The results and goals of the claims, improved systemic absorption compared to subcutaneous delivery, are also the same. Thus, contrary to the Examiner's contention, Applicants assert that to search and examine Claims 65-74 (Group IV), Claims 75-96 (Group V) and Claims 99-118 (Group VII) involving methods for administering substances to the dermal space would not be a serious burden on the Examiner. The M.P.E.P. § 803 (Eighth Edition, Rev. 2, May 2004) states:

> If the search and examination of an entire application can be made *without serious burden*, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. (emphasis supplied)

Thus, in view of M.P.E.P. § 803, all of the claims of Groups IV, V, and VII should be searched and examined in the subject application. Accordingly, Applicants respectfully request that the Restriction Requirement Under 35 U.S.C. § 121 be modified such that claims 65-74, Claims 75-96 and Claims 99-118 are examined in one application.

Notwithstanding the above, and in order to be fully responsive to the outstanding restriction requirement, Applicants hereby provisionally elect, with traverse, to prosecute the claims of Group VII (Claims 99-118), drawn to methods of administering a substance to the dermis to achieve improved systemic absorption as compared to bolus subcutaneous administration, without prejudice to Applicants' right to purse the non-elected subject matter in related applications.

The Examiner further indicates that if any one of Groups I-VII is elected, the Applicant is required to elect a single species of the 27 listed allegedly patentably distinct species. Applicant notes that in view of the cancellation of Claims 1-64, the Examiner's species' classifications is moot, especially in reference to species to improved pharmacokinetics, species to administration time, species to substance molecular weight, and species to improved pharmacokinetics. However, in order to be fully responsive, Applicant provisionally elects the species drawn to heparin for examination on the merits. Applicants

believe that Claims 99-118 each read on the elected species.

Entry of the remarks made herein is respectfully requested. The Examiner is invited to contact the undersigned with any questions concerning the foregoing.

CONCLUSION

In light of the above amendments and remarks, Applicant respectfully requests that the Examiner enter the amendments and consider the remarks made herein. The Examiner is invited to call the undersigned attorney if a telephone call could help resolve any remaining items.

Respectfully submitted, by Jacqueline Benn
Reg No. 43,492

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Laura A. Coruzzi 30,742
Laura A. Coruzzi (Reg. No.)

JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3939